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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,623	09/12/2001	Ryan McGuinness	41618	6108

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,623	Applicant(s) MCGUINNESS ET AL.	
	Examin r Ulrike Winkler	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7, 11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper Nos. 7 and 11, are attached to the instant Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "functional equivalent thereof" is indefinite, because defining a product merely by a functional attribute fails to describe the product. The best way to describe a product would be to describe the structure in addition to some functional attributes.

For example claiming a product that it is made of a rubber like material which is squishy and bouncy does not provide the ordinary artisan with any knowledge regarding the structure and the ordinary artisan would not know that the claimed product is defining a rubber ball. Therefore, claiming a product by function alone fails to describe the structure of the product. Without knowledge of the structure of the product the ordinary artisan cannot envision what is contemplated by the hypothetical rubber ball claim. Adding a structural feature, such as

spherical, to the claimed product provides more information to envision a rubber ball or a balloon, narrowing the possibilities.

In this instance the claim is drawn to a "RRE or functional equivalent thereof", neither the specification nor the art in general defines what is encompassed by the "functional equivalent", is this a mutant RRE or is this a new yet undiscovered structure that happens to have the same function of the RRE but is not RRE. Clarification of what is encompassed by the term "functional equivalent" is required.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a RRE element or "functional equivalent thereof", defining a product merely by a functional attribute fails to describe the product. Neither the specification nor the art in general defines what is encompassed by the "functional equivalent", therefore the specification as filed fails to sufficiently describe the structure of these functional equivalents.

Applicants have not provided any information regarding the necessary structural elements that need to be conserved in order to fall within the term "function equivalent thereof."

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are drawn to a RRE element or "functional equivalent thereof" (specification page 5, lines 10-14), defining a product merely by a functional attribute fails to describe the product.

The claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims. Such an analysis does not need to specifically enumerate (points 1-8) but only needs to have a select few of the factors present discussed in a rejection.

Neither the specification nor the art in general have disclosed how to make or determine that a particular structure will be a functionally equivalent of RRE. The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as filed application or which would have

been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined homologous regulatory elements that functionally operate equivalently to yield selectable splicing of the *gag/pol* sequences. The instant fact pattern fails to disclose any particular structure for the claimed RRE element or "functional equivalent thereof". The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to have prepared the claimed "functional equivalent thereof" without undue experimentation.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(a) or 102(e) as being anticipated by Carrano et al. (U.S. Pat. No. 5,739,118; see IDS).

The instant invention is drawn to a nucleic acid construct comprising a promoter, a splice donor site, a gag/pol coding region, a RRE element a splice donor site and a selectable marker. A coding sequence is defined in the art as that part of the nucleic acid molecule that can be transcribed and translated into a polypeptide using the genetic code. Because gag and pol are polyproteins a sequence less than the entire gag/pol region will fall within the meaning of the term "a gag/pol coding region".

Carrano et al. disclose a nucleic acid construct (see figure 4 and 5, and example 36) that comprises gag/pol and RRE with a splice acceptor site. The construct is inserted into a plasmid selected from A-D (see figure 4), and the plasmid contains a selectable marker. The reference also indicates that in some embodiments there is a splice donor upstream of the gag transnational start codon (see column 22, lines 25-30). Therefore, the instant invention is anticipated by Carrano et al

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Yu et al. (Journal of Virology, 1996; see IDS).

The instant invention is drawn to a nucleic acid construct comprising a promoter, a splice donor site, a gag/pol coding region, aRRE element a splice donor site and a selectable marker. A coding sequence is defined in the art as that part of the nucleic acid molecule that can be transcribed and translated into a polypeptide using the genetic code. Because gag and pol are polyproteins a sequence less than the entire gag/pol region will fall within the meaning of the term "a gag/pol coding region".

Yu et al. disclose a nucleic acid construct (see figure 2) that comprises gag/pol and RRE. The construct is inserted into a cell in order to produce using the tetracycline inducible system (see figure 1). In a cell that is able to propagate the retroviral vector and produce particles, gag/pol and env constructs are present as well as the HVP construct (see figure 2) here HVP and the envelope construct produce REV protein which has an effect on the RRE in all three constructs (binding to the RRE). In this instance the HVP is the first construct and the pTIRevENV is the second expression cassette. Therefore, the instant invention is anticipated by Yu et al.

Claims 1 and 2 is rejected under 35 U.S.C. 102(a) as being anticipated by Kaul et al. (Virology, September 1998).

The instant invention is drawn to a nucleic acid construct comprising a promoter, a splice donor site, a gag/pol coding region, aRRE element a splice donor site and a selectable marker. A coding sequence is defined in the art as that part of the nucleic acid molecule that can be

transcribed and translated into a polypeptide using the genetic code. Because gag and pol are polyproteins a sequence less than the entire gag/pol region will fall within the meaning of the term "a gag/pol coding region".

Kaul et al. disclose a nucleic acid construct (see figure 1) that comprises gag/pol and RRE, specifically pHVP and pHIV-GIP. In a cell that is able to propagate the retroviral vector and produce particles, gag/pol and env constructs are present as well (see page 173, column1, 1st paragraph). In this instance the HVP or pHIV-GIP is the first construct and the pTIRevENV is the second expression constuct. Therefore, the instant invention is anticipated by Kaul et al

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 9/30/05